



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 23, 2017

Mr. Bob MacDonald
Regulatory Agent for,
Crosstex International, Inc.
10 Ranick Road
Hauppauge, NY 11788

Subject: Notification per PRN 98-10 – Product Name Change
Product Name: Liquid Ultra Solution 2
EPA Registration Number: 74245-6
Application Date: March 7, 2017
Decision Number: 527005

Dear Mr. MacDonald:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

The product file will be changed to reflect the following:

Old Product Name: Sterilex Liquid Ultra Solution 2

New Product Name: Liquid Ultra Solution 2

If you have any questions, you may contact Karen M. Leavy at (703)-308-6237 or via email at Leavy.Karen@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Karen M. Leavy Esq,". The signature is written in a cursive style with a large initial 'K' and a trailing flourish.

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

[Crosstex Company Logo]

NOTIFICATION

74245-6

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

03/23/2017

Liquid Ultra Solution 2

[(This is a 2 part liquid product)]

[This is part two of a two-part product]

[This is part of a two-part product]

Always Use With [Crosstex] Liquid Ultra Solution 1

Ready to Use – Do Not Add Water

Think Pink Once A Week®

- Removes* biofilm from dental unit water lines
- Prevents and suppresses formation of biofilm in dental unit water lines
- Kills biofilm bacteria
- Maintains dental unit water line effluent water <500 cfu/ml

Note: Do Not Use Thin Walled Polyethylene Terephthalate (PET) Bottles. We Recommend Either A High Density Polyethylene Bottle With A Minimum Thickness Of 0.08 Inches Or A High/Low Density Polyethylene Blend With A Minimum Thickness Of 0.14 Inches

*Laboratory studies [have shown] [show] >90% removal

Active Ingredients:

n-Alkyl (C₁₂ 68%, C₁₄ 32%) dimethyl ethylbenzyl ammonium chloride 0.5%

n-Alkyl (C₁₄ 60%, C₁₆ 30%, C₁₂ 5%, C₁₈ 5%) dimethyl ethylbenzyl ammonium chloride 0.5%

Other Ingredients 99.0%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

(For containers less than or equal to 1 gallon: see package insert [or hang tag] prior to use for use instructions, [first aid, and precautionary information] [precautionary and first aid information].)

[Manufactured for:] Crosstex International, Inc.

Corporate Office: 10 Ranick Road, Hauppauge, NY 11788-4209 USA

Website: www.crosstex.com **E-mail:** crosstex@crosstex.com

California · Colorado · Georgia · New York · Pennsylvania · Argentina · Japan

Singapore · The Netherlands

[Made in [the] USA]

[Made in USA logo]

EPA REG. NO. 74245-6

EPA EST. NO. 73516-MD-001

NET CONTENTS _____

LOT NO. _____

Important Notice:

Before using [Crosstex] Liquid Ultra Solution 2 please read the following information.

- 1.This product is to be used in conjunction with regular testing of dental unit water. [Testing frequency must comply with user’s practice protocol.]
- 2.The manufacturer of the dental unit should be consulted before use of this product [about] [regarding] compatibility of [Crosstex] [the]Liquid Ultra Solution [2] with the dental unit.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Always Use [Crosstex] Liquid Ultra Solution [2][1] with [Crosstex] Liquid Ultra Solution [1][2]

1. Initial Start-Up Treatment: Treat the Dental Unit Water Lines (DUWL) for three consecutive nights [starting on Monday].
2. Routine Treatment: Treat DUWL one night/week (Monday-Thursday recommended) after initial Start-up treatment.
3. If two or more weekly treatments are skipped, repeat initial start-up treatment.

How to Apply [Crosstex] Liquid Ultra Solutions 1 [&] [and] 2:

1. Add one bottle (3 ounces) of [Crosstex] Liquid Ultra Solution 1 and one bottle (3 ounces) of [Crosstex] Liquid Ultra Solution 2 [in a measuring cup or other empty container and stir]. [Pour appropriate amount of the combined mixture] into an empty external dental unit water bottle [and stir]. Do not use PET bottles (see note [below] [above]). [After [Crosstex] Liquid Ultra Solution 1 and [Crosstex] Liquid Ultra Solution 2 have been mixed together use within 24 hours].[Once mixed together, solution must be used within 24 hours.]
2. Run [Crosstex] Liquid Ultra mixture through the system until the pink [mixture] [solution]appears at the end of [the] [each] Air/Water syringe[s] and handpiece lines. [Depending on the number of lines in the unit, there may be residual solution in the bottle.] Always remove the handpiece. It may be advisable to remove coupler depending on the type of coupler[.] [,][Contact] [contact] manufacturer for specific recommendations.
3. Allow the [Crosstex] Liquid Ultra mixture to [sit in the unit] [remain in the lines] overnight. [To prevent accidental spillage, ([Place] [place] the ends of water lines into a sink or [cuspidor][container] in case any pink mixture drips overnight).

[NOTE: Do not allow the Liquid Ultra mixture to remain in the lines for more than 24 hours.]

4. [At the beginning of the next workday, discard any remaining [Crosstex] Liquid Ultra mixture. Rinse the external water bottle with water.] {or}
[The following morning, flush any remaining [Crosstex] Liquid Ultra mixture from the bottle, through either the air/water syringe or handpiece lines until the external water bottle is empty.]
5. [Fill the external water bottle with water. Flush each line (Air/Water syringe, handpiece lines) until the bottle is empty.]
{or}
[Remove and rinse the external water bottle with water and then fill with water.]
6. [Flush each line (air/water syringe and handpiece lines) until the water runs clear and the bottle is empty.]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. CAUTION. Causes moderate eye irritation and harmful if swallowed. Avoid contact with eyes, skin or clothing. Do not get in eyes [on] skin or [on] clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, egg whites, gelatin, or if these are not available, drink large quantities of water. Avoid alcohol.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by improper storage or disposal.

PESTICIDE STORAGE: Keep product in closed original container when not in use. Store in a cool, dry area away from potential sources of heat, open flames, sunlight or other chemicals. DO NOT store above 30°C (or 86°F).

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. If rinsate cannot be used, follow pesticide disposal instructions. If not triple rinsed these containers are acute hazardous wastes and must be disposed in accordance with local, state and federal regulations. Triple rinse [or pressure rinse] container (or equivalent) promptly after emptying.

[(NOTE TO REVIEWER: The following language is for nonrefillable containers having a capacity of 5 gallons or less) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable containers having a capacity of 5 gallons or less when "or pressure rinse" appears in the above Container Disposal statement)

Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow

begins to drip.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable containers having a capacity greater than 5 gallons Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.]

[(NOTE TO REVIEWER: The following language is optional for nonrefillable containers having a capacity Greater than 5 gallons when “or pressure rinse” appears in the above Container Disposal statement) Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip.]

*[(NOTE TO REVIEWER: *Optional Text*]*

[COMBINATION PACKAGE]

[For Technical Assistance Call **1-888-276-7783**]

[Please consult the directions for use for specific instructions.]

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